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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,836	01/29/2004	David L. Kaplan	1322.1026-005	2982
21005	7590	12/26/2007		
HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133			EXAMINER ZEMAN, ROBERT A	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 12/26/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/767,836

Applicant(s)

KAPLAN ET AL.

Examiner

Robert A. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8-13-2004</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-13 are pending and currently under examination.

Information Disclosure Statement

The Information Disclosure Statement filed on 8-13-2004 has been considered. An initialed copy is attached hereto.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. Additionally, **the current status** of each prior nonprovisional application must be provided.

Claim Rejections

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Gutnick et al. (U.S. Patent 4,311,829).

The instant claims are drawn to formulations comprising an emulsan and an antigen.

Gutnick et al. disclose a composition comprising an antigen and an emulsan wherein the emulsan is secreted from *Acinetobacter Sp.* ATCC 31012 (RAG-1) and its mutants Gutnick et al. further disclose that the emulsan composition comprises an emulsan analog wherein the analog has a fatty acid chain length of 10-18 carbons (see column 6).

Moreover, Gutnick et al. disclose formulations comprising emulsans and Freund's complete adjuvant. (see column 26). Since Freund's complete adjuvant comprises *Mycobacterium tuberculosis* constitutes an antigen as defined by the specification (see page 8, lines 1-23). The recited limitation "emulsan adjuvant" is interpreted as an intended use and therefore is given no patentable weight. Since all the rejected claims are drawn to compositions comprising the same components as those compositions disclosed by Gutnick et al., they would, in absence of evidence to the contrary, possess the same chemical and immunological properties. Hence, the formulations disclosed by Gutnick et al. anticipate all the limitations of the instant claims.

Finally, with regard to claim 10, although Gutnick et al. disclose the same product they do not disclose the claimed method of making. However, it should be noted that the instant claims constitute Product-by-Process type claims. In Product-by-Process type claims, the process

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of producing the product is given no patentable weight since it does not impart novelty to a product when the product is taught by the prior art. See *In re Thorpe*, 227 USPQ 964 (CAFC 1985); *In re Marosi*, 218 USPQ 289, 292-293 (CAFC 1983) and *In re Brown*, 173 USPQ 685 (CCPA 1972). Consequently, even if a particular process used to prepare a product is novel and unobvious over the prior art, the product *per se*, even when limited to the particular process, is unpatentable over the same product taught in by the prior art. See *In re King*, 107 F.2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); *In re Merz*, 97 F.2d 599, 601, 38 USPQ 143-145 (CCPA 1938); *In re Bergy*, 563 F.2d 1031, 1035, 195 USPQ 344, 348 (CCPA 1977) *vacated* 438 US 902 (1978); and *United States v. Ciba-Geigy Corp.*, 508 F. Supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979). Finally, since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gutnick et al. (U.S. Patent 4,311,829) and Leahy et al. (Journal of Bacteriology, 1993, Vol. 175, No. 6, pages 1838-1840 – IDS filed on 8-13-2004).

The instant claims are drawn to formulations comprising an emulsan and an antigen wherein the emulsan is secreted from a transposon mutant

Gutnick et al. disclose a composition comprising an antigen and an emulsan wherein the emulsan is secreted from *Acinetobacter Sp.* ATCC 31012 (RAG-1) and its mutants Gutnick et al. further disclose that the emulsan composition comprises an emulsan analog wherein the analog has a fatty acid chain length of 10-18 carbons (see column 6).

Moreover, Gutnick et al. disclose formulations comprising emulsans and Freund's complete adjuvant (see column 26). Since Freund's complete adjuvant comprises *Mycobacterium tuberculosis* constitutes an antigen as defined by the specification (see page 8, lines 1-23). The recited limitation "emulsan adjuvant" is interpreted as an intended use and therefore is given no patentable weight. Since all the rejected claims are drawn to compositions comprising the same components as those compositions disclosed by Gutnick et al., they would, in absence of evidence to the contrary, possess the same chemical and immunological properties.

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Hence, the formulations disclosed by Gutnick et al. anticipate all the limitations of the instant claims.

Gutnick et al. differs from the instant invention in that they don't explicitly disclose that the *Acinetobacter sp.* mutants are transposon mutants

Leahy et al. disclose methods of using transposons to mutate *Acinetobacter calcoaceticus* RAG-1 (see abstract). Consequently, it is deemed that since the use of transposon mutation was known in the art at the time of the invention its use constitutes an obvious variation of the disclosed composition.

Finally, with regard to claim 10, although Gutnick et al. disclose the same product they do not disclose the claimed method of making. However, it should be noted that the instant claims constitute Product-by-Process type claims. In Product-by-Process type claims, the process of producing the product is given no patentable weight since it does not impart novelty to a product when the product is taught by the prior art. See *In re Thorpe*, 227 USPQ 964 (CAFC 1985); *In re Marosi*, 218 USPQ 289, 292-293 (CAFC 1983) and *In re Brown*, 173 USPQ 685 (CCPA 1972). Consequently, even if a particular process used to prepare a product is novel and unobvious over the prior art, the product *per se*, even when limited to the particular process, is unpatentable over the same product taught in by the prior art. See *In re King*, 107 F.2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); *In re Merz*, 97 F.2d 599, 601, 38 USPQ 143-145 (CCPA 1938); *In re Bergy*, 563 F.2d 1031, 1035, 195 USPQ 344, 348 (CCPA 1977) *vacated* 438 US 902 (1978); and *United States v. Ciba-Geigy Corp.*, 508 F. Supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979). Finally, since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, the burden

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is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Claims 1-4 and 6-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gutnick et al. (U.S. Patent 4,311,829) and Reese et al. (PNAS 1978, Vol. 75 No., pages 959-962).

The instant claims are drawn to formulations comprising an emulsan and a dinitrophenol-keyhole limpet hemocyanin conjugate.

Gutnick et al. disclose a composition comprising an antigen and an emulsan wherein the emulsan is secreted from *Acinetobacter Sp.* ATCC 31012 (RAG-1) and its mutants Gutnick et al. further disclose that the emulsan composition comprises an emulsan analog wherein the analog has a fatty acid chain length of 10-18 carbons (see column 6).

Moreover, Gutnick et al. disclose formulations comprising emulsans and Freund's complete adjuvant (see column 26). Since Freund's complete adjuvant comprises *Mycobacterium tuberculosis* constitutes an antigen as defined by the specification (see page 8, lines 1-23). The recited limitation "emulsan adjuvant" is interpreted as an intended use and therefore is given no patentable weight. Since all the rejected claims are drawn to compositions comprising the same components as those compositions disclosed by Gutnick et al., they would, in absence of evidence to the contrary, possess the same chemical and immunological properties. Hence, the formulations disclosed by Gutnick et al. anticipate all the limitations of the instant claims.

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Gutnick et al. differs from the instant invention in that they don't explicitly a composition comprising an emulsan and a dinitrophenol-keyhole limpet hemocyanin conjugate.

Reese et al. disclose compositions comprising keyhole limpet hemocyanin and complete Freund's adjuvant (see abstract). Reese et al. further disclose that the antigens can be used to generate specific antibodies subtypes (see abstract). Given that Gutnick et al. disclosed a composition comprising an Freund's complete adjuvant and an emulsan wherein the emulsan is secreted from *Acinetobacter calcoaceticus* RAG-1 and that Reese et al. disclose a polypeptide antigen coupled to a keyhole limpet hemocyanin carrier it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make a composition comprising a polypeptide antigen coupled to keyhole limpet hemocyanin. One would have been motivated to make such a composition because in order to take advantage of the induction of the specific antibody subtypes associated with the use of KLH.

Finally, with regard to claim 10, although Gutnick et al. disclose the same product they do not disclose the claimed method of making. However, it should be noted that the instant claims constitute Product-by-Process type claims. In Product-by-Process type claims, the process of producing the product is given no patentable weight since it does not impart novelty to a product when the product is taught by the prior art. See *In re Thorpe*, 227 USPQ 964 (CAFC 1985); *In re Marosi*, 218 USPQ 289, 292-293 (CAFC 1983) and *In re Brown*, 173 USPQ 685 (CCPA 1972). Consequently, even if a particular process used to prepare a product is novel and unobvious over the prior art, the product *per se*, even when limited to the particular process, is unpatentable over the same product taught in by the prior art. See *In re King*, 107 F.2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); *In re Merz*, 97 F.2d 599, 601, 38 USPQ 143-145 (CCPA

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1938); *In re Bergy*, 563 F.2d 1031, 1035, 195 USPQ 344, 348 (CCPA 1977) *vacated* 438 US 902 (1978); and *United States v. Ciba-Geigy Corp.*, 508 F. Supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979). Finally, since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



ROBERT A. ZEMAN
PRIMARY EXAMINER

December 18, 2007